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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,352	07/25/2003	Vladimir Knezevic	6457-65777	2321

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KLARQUIST SPARKMAN, LLP
One World Trade Center
Suite 1600
121 S.W. Salmon Street
Portland, OR 97204

EXAMINER

PADMANABHAN, KARTIC

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,352	KNEZEVIC ET AL.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 June 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 22-28 and 32-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 22-28 and 32-44 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Specification

1. The use of the trademark GeneChip (page 2) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. The disclosure is objected to because of the following informalities: in the amendment to the specification dated 7/25/03, applicant has included a paragraph cross referencing related applications; however, applicant has mistakenly referenced App. No. 09/418,990, rather than 09/718,990, and since the application has already issued, applicant should also change “will issue” to “issued.”

Appropriate correction is required.

Claim Objections

3. Claims 39-43 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s) or amend the claim(s) to place the claim(s) in proper dependent form. Claims 39-43 all limit the nature of the sample, or in the case of claim 43, where the sample is contained; however, the sample is analyzed using the kit of the claims, and is not itself a part of the kit.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 27 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The term "low" in claim 27 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. Claim 38 recites the limitation "said porous substrate." There is insufficient antecedent basis for this limitation in the claim. It appears that the claim should depend from claim 37, rather than 36.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 22-25, 27-28, 33-36, and 39-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Christian (EP 0 139 373 A1). The reference discloses a multiple immunoassay system comprising a microassay rod adapted for screening biologic fluids for the presence of various analytes. The rod is based on a column of spaced detection layers with each detection layer including a binding amount of a known binding agent. Up to 250 or more detection layers may be formed within one rod (abstract). The system

of the invention can be used to quantify substances that participate in any number of binding reactions, including antigen-antibody or nucleic acid hybridization (Page 4, lines 20-25). Specifically, the rod of the invention can be used to detect nucleic acid hybridization of nucleic acids attached to nitrocellulose filters (Page 7, lines 32-35). The immunoassay carried out in each detection layer may be directly measured by a suitable detection system (Page 7, lines 15-20). Each detection layer is made up of a suitable absorbent, such as nitrocellulose, plastics, nylons, and various other synthetic fibers and supports that do not prevent binding reactions (Page 8, lines 17-28). It is inherent that the membranes of the invention are under 30 microns in thickness. In addition, since antibodies may be applied to the membranes to bind antigen, it is inherent that at some point, the antibodies are stored in some type of container prior to use.

10. Claims 22-25, 27-28, 33-35, and 39-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Nieuwkerk et al. (US Pat. 5,438,128). The reference discloses a method for rapid purification of nucleic acids, such as RNA and DNA, using layered membranes. The device of the reference comprises a membrane assembly comprised of microporous, polymeric membranes functionalized with ion-exchange groups. The reference also discloses a kit comprised of the device of the reference, as well as premeasured volumes of reagents for use with the biological samples (Col. 2, lines 9-41). The device and method of the reference can be used with specimens such as human bodily fluids and tissues (Col. 2, lines 64-68). The membranes or solid support of the reference can be made up of cellulose, nylon, PVDF, polypropylene, or other porous material (Col. 5, lines 28-35). In addition, an elution, or transfer buffer, is also

contemplated for use with the device. It is inherent that the membranes of the invention are under 30 microns in thickness.

11. Claims 22-23, 25, 27-28, 34-35, and 39-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Imai et al. (US Pat. 5,057,438). The reference discloses a method for the determination of a plurality of species of antibodies or antigens wherein a plurality of membranes are formed with an antigen or antibody on an electrophoretic carrier. These reaction membranes are superposed. Antibodies or antigen corresponding to the species located on the membranes are then added and electrophoretically moved to the reaction membranes, where binding occurs. The reaction membranes are then separated and detection of the analyte of interest on the membranes occurs on each membrane (Cols. 8-9). It is inherent that the membranes of the invention are under 30 microns in thickness. In addition, since antibodies may be applied to the membranes to bind antigen, it is inherent that at some point, the antibodies are stored in some type of container prior to use.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 32 and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (EP 0 139 373 A1) or Nieuwkerk et al. (US Pat. 5,438,128) in view of Hunkapiller et al. (US Pat. 6,232,067).

Christian and Nieuwkerk et al. teach analytical devices, kits, and methods, as previously discussed. However, the references do not teach the use of polycarbonate as the substrate.

Hunkapiller et al. teach methods for analyzing various polynucleotides. The reference also teaches the use of a solid support made up of polycarbonate or other polymers for the immobilization of nucleic acids.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the polycarbonate substrate of Hunkapiller et al. with the methods and kits of Christian or Nieuwkerk et al. because both Christian and Nieuwkerk

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et al. teach that any porous substrate material would be suitable with their methods.

Since Hunkapiller et al. teach the use of polycarbonate, which is porous in nature, for the immobilization of nucleic acids, one would have had a reasonable expectation of success in using polycarbonate with the methods of Christian and Nieuwkerk et al. In addition, although the combination of references may not specifically teach that the plurality of membranes has a porous substrate with a thickness between 4 and 30 microns, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a substrate with the specified thickness range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

16. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (EP 0 139 373 A1) or Nieuwkerk et al. (US Pat. 5,438,128) in view of Pipas et al. (US Pat. 6,168,929 B1).

Christian and Nieuwkerk et al. teach analytical devices, kits, and methods, as previously discussed. However, the references do not teach the use of an antibody cocktail.

Pipas et al. teach the use of an antibody cocktail to probe analytes blotted onto PVDF membranes.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibody cocktail of Pipas et al. with the methods and kits of Christian or Nieuwkerk et al. because one could have used any antibody with the kits

of the references, depending on the analyte(s) of interest, with a reasonable expectation of success.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 22-28 and 32-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 92-100 of US 2004/0081979 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite kits comprising

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membrane arrays and containers of probes to detect biomolecules, and one of ordinary skill in the art would recognize that the claims read on each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

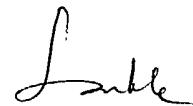
Claims 22-28 and 32-44 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

06/11/04